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07/838/675

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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02/838,675 02/21/92 FALK

R PT-1039

EXAMINER

18M02/1122

MARCELO K. SARKIS
175 COMMERCE VALLEY DRIVE, WEST
STE. 200
THORNHILL, ONTARIO, L3T 7P6 CANADA

ART UNIT

PAPER NUMBER

1806

13

11/22/93

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

for Restriction Purposes Only

This application has been examined Responsive to communication filed on 7/20/93 This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 1 - 25 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims _____ are rejected.

5. Claims _____ are objected to.

6. Claims 1 - 25 are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

18 November 1993

5 **15.** The restriction made in the previous Office Action is withdrawn. The following new restriction is being made.

10 **Group I.** Claims 1-5 and 21-25, drawn to a pharmaceutical composition comprising hyaluronic acid, classified in Class/subclass 514/23+ and 536/123.1.

15 **Group II.** Claims 6-20, drawn to a method of treating a disease or condition of the skin, and the transdermal delivery of a therapeutically effective amount of a drug, classified in Class/subclass 514/23+, and 424/78.02.

20 **16.** The inventions are distinct, each from the other because of the following reasons:

25 Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the pharmaceutical composition can be used in a materially different way, such as to treat different diseases or conditions, such as basal cell carcinoma, fungal lesion, psoriasis, corns, and hair loss, as claimed.

30 **17.** Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

35 **18.** This application contains claims directed to the following patentably distinct species of the claimed invention.

40 A. If applicants elect Group II, then applicants are required to elect a species from within that Group.

Group II:

45 Species A - basal cell carcinoma (claims 6, 16)

50 Species B - actinic keratoses lesions (claims 6, 16)

Species C - fungal lesions (claims 6, 16)

Species D - epidermal "liver" spots and like lesions (claims 6, 16)

5 Species E - squamous cell tumors (claims 6, 16)

Species F - metastatic cancer of the breast to the skin (claims 6, 16)

10 Species G - primary and secondary metastatic melanoma in the skin (claims 6, 16)

Species H - genital warts (claims 6, 16)

Species I - cervical cancer (claims 6, 16)

15 Species J - human papilloma virus, including cervical (claims 6, 16)

Species K - plaque-type and nail bed psoriasis (claims 6, 16)

20 Species L - corns on the feet (claims 6, 16)

Species M - hair loss on the heads of pregnant women (claims 6, 16)

25 The methods are drawn to methods of treating different and unrelated diseases or skin conditions which have different etiologies and are treated with different reagents. Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7-15, 19, and 20 are generic.

17 18,

30 35 19. Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

40 Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

5 20. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10 21. Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15 22. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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25 23. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone numbers are (703) 308-4227 and (703) 305-3014.

30 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Krikorian whose telephone number is (703) 308-3964. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

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J. G. Krikorian, Ph.D.
J. G. Krikorian, Ph.D.
Patent and Trademark Office

David L. Lacey
DAVID L. LACEY
SUPERVISORY PATENT EXAMINER
GROUP 180
11/18/93